

CHARGE: 501 (b)—the article, while held for sale, purported to be a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 5-13-57. Default—destruction.

5330. Digitoxin powder. (F. D. C. No. 40111. S. No. 56-160 M.)

QUANTITY: 2 25-gram btl. at Chicago, Ill.

SHIPPED: 1-16-57, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * Assay: Digitoxin 99.10% Loss on drying 0.62%."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 85 percent of digitoxin when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent.

LIBELED: 3-28-57, N. Dist. Ill.

CHARGE: 501 (b)—The article, when shipped, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4-23-57. Default—destruction.

5331. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40121. S. Nos. 38-204/5 M.)

QUANTITY: 1 6-gram btl. and 1 40,000-tablet drum at St. Louis, Mo.

SHIPPED: 12-14-56, from New York, N. Y., by H. Reisman Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking"; (drum) "0.2 mg. C. T. Digitoxin."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from a portion of the bulk *digitoxin powder* shipped on the above date.

Examination showed that the powder contained not more than 83.5 percent digitoxin and that the tablets contained not more than 0.156 milligram of digitoxin per tablet when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay results be not less than 90 percent of the labeled amount of digitoxin.

LIBELED: 4-4-57, E. Dist. Mo.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4-30-57. Default—destruction.

5332. Digitoxin tablets. (F. D. C. No. 40162. S. No. 38-211 M.)

QUANTITY: 34,772 tablets at St. Louis, Mo.

SHIPPED: 7-6-56 and 11-26-56, from New York, N. Y.

LABEL IN PART: "109a Compressed Tablets Digitoxin, 0.2 mg. Each Tablet Contains: Digitoxin, U. S. P. * * * 0.2 mg."